Remarks

This amendment is in response to the Non-final Office Action mailed August 9, 2006.

Applicants have amended claim 4 to correct typographical errors. Polyethylene and polypropylene have been deleted and ethylene and propylene have been added. Support is found at least from page 8, lines 6-8 and claim 16 as originally filed. No new matter has been added.

Rejections

35 U.S.C. §102(e)

Claims 1-21 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Wang et al. (U.S. 6,939,321).

The Office Action asserts that the balloon in figure 5 of Wang et al., "...comprises a first plasma polymerized layer which forms the outer layer (33) of the balloon and a second plasma polymerized layer which is considered to form on the inner layer (34) of the balloon." The Office Action further asserts that as to the method claims, "...Wang et al. is inherently capable of performing the method steps as recited in the claimed invention."

Applicants traverse the rejection.

Independent claim 1 of the present invention is directed to a dilatation balloon having at least one first ***plasma polymerized*** layer which forms the outer most layer of the balloon.

Applicants submit that Wang et al. discloses in one aspect:

....a balloon in which the balloon first layer has at least a section with a ***gas***

> ***plasma-etched or chemical solution-etched surface***. The etched surface improves the strength of the bond between the first layer and the second layer and/or the catheter shaft.

Summary of the Invention, col. 2, lines 27-31.

The first layer may be expanded polytetrafluoroethylene, ultra high molecular weight polyolefin, ultra high molecular weight polyethylene, porous polyethylene, porous polypropylene, and porous polyurethane. See claim 2.

The second layer may be an elastomeric polymeric material bonded to the inner surface of the first layer. See claim 10.

While the first and second layer of Wang et al. are polymeric, ***neither layer is plasma polymerized,*** which results in crosslinking. The plasma polymerized layer as recited in claim 1 of the present invention is produced by ***condensation and crosslinking of gaseous monomers*** on the surface of the medical device resulting in a highly crosslinked layer. See at least the Summary of the Invention, page 3, lines 10-16.

What is disclosed by Wang et al. is a first inner layer which may have at least a section of its inner surface and at least a section of its outer surface which is gas plasma-***etched*** or chemical solution-***etched*** for improved bonding to either the second layer or a catheter shaft. See column 2, lines 22-38. Wang et al. define "etching" as the following:

> The terminology "etch" used herein in relation to the embodiment involving a plasma gas treatment should be understood to refer generally to the modification of the polymer which results from the gas-plasma treatment. In one embodiment, the gas plasma etched/treated surface is formed using an ammonia plasma (e.g., treatment with ammonia anions by reaction in an ammonia gas filled plasma chamber). Alternative gases may be used in the gas plasma etching including argon, helium, hydrogen, oxygen, and air, in addition to or instead of the ammonia gas. The ammonia gas plasma etching provides an amine functionality on and beneath the surface of the first layer (e.g., the ePTFE layer) of the balloon, for improved bondability.

Column 4, lines 31-44.

Wang et al. provides one example of this as removing fluorine atoms from ePTFE, and introducing hydroxyl, carbonyl and carboxyl functionalities on and beneath the surface of the ePTFE. See column 4, lines 14-20. While this is a chemical change to the polymer material, it does not involve polymerization, in particular it does not involve plasma polymerization of the polymer material wherein the material is crosslinked on the surface. Wang et al. fails to disclose polymerization of either the first or second layer, much less ***plasma polymerization*** of the first or second layer disclosed therein.

Modification of a polymer by plasma or chemical etching is a process which is readily distinguished from plasma polymerization as is known to those of skill in the art. Plasma etching involves modification of the polymer, but not polymerization or crosslinking of the polymer as in ***plasma polymerization***. See, for example, http://en.wikipedia.org/wiki/Plasma_etching (copy of web page attached).

Furthermore, ***a plasma polymerized layer can be distinguished*** from an uncrosslinked layer as those disclosed by Wang et al., and in fact, can be readily distinguished from ***a conventionally polymerized*** polymer layer using analytical techniques as is known to those of ordinary skill in the art. See, for example, http://www.answers.com/topic/plasma-polymerization and http://www.eurobonding.or/Englisch/Oberflaechen/Plasma_polymerization.htm (copy of web pages attached). As shown in the latter, plasma polymerization results in a crosslinked chemical structure having higher crosslink density, a difference which is readily detectable by current analytical techniques.

Therefore, independent claim 1 of the present application is not anticipated by

Wang et al. because Wang et al. does not disclose that either the first layer or the second layer are plasma polymerized, and a plasma polymerized layer can be readily distinguished from either an uncrosslinked polymer layer as disclosed by Wang et al., or from a conventionally crosslinked polymer layer. Claims 2-8 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable over Wang et al.

Independent claim 9, directed to an implantable medical device, is patentable over Wang et al. for at least the reasons that claim 1 is patentable. Independent claim 9 also recites the feature of having a plasma polymerized outer layer which is not disclosed by Wang et al. Claims 10-13 depend from claim 9 and are patentable for at least the reasons that claim 9 is patentable over Wang et al.

The independent method claim 14 of the present application recites a step wherein a monomer composition is exposed to electromagnetic waves to form the plasma wherein said monomers are condensed and crosslinked on the surface of a catheter balloon.

As Wang et al. fails to suggest crosslinking of either the first polymeric layer or the second polymeric layer disclosed therein, claim 14 is also not anticipated by Wang et al. Claims 15-21 depend from claim 14 and are patentable for at least the reasons that claim 14 is patentable over Wang et al.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1-21 under 35 U.S.C. §102(e) as anticipated by Wang et al., U.S. Patent No. 6,939,321.

Applicants have added a new claim 22 which depends from claim 1 and is directed to the thickness of the plasma polymerized layer, a feature which is also not disclosed by Wang et al.

CONCLUSION

Claims 1-22 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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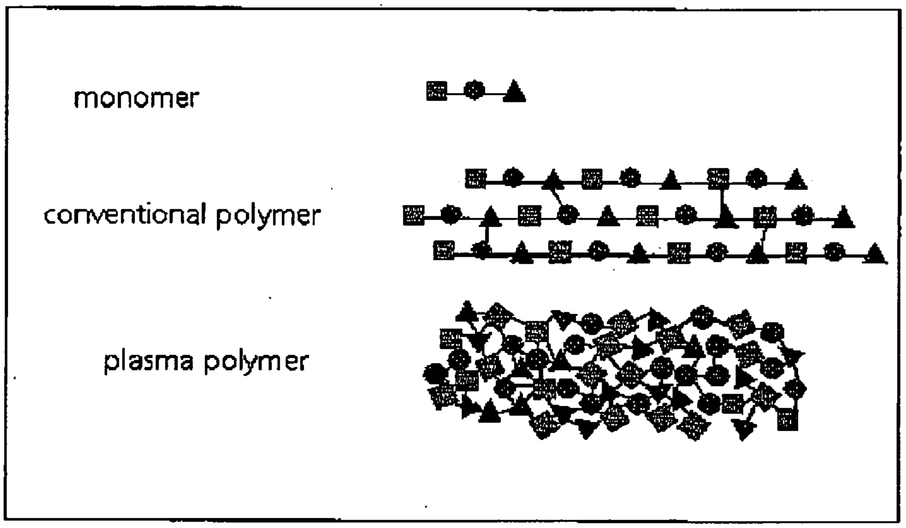
Plasma polymerization

Plasma polymerization is a procedure, in which gaseous monomers, stimulated through a plasma, condense on freely selectable substrates, as high cross-linked layers. Condition for this process is the presence of chain-producing atoms, such as carbon, silicium or sulfur, in the working gas. As the monomer molecules in plasma, for the most part, become shattered into reactive particles, there remain at most, only partially preserved chemical structures of the output gases in the product, which results in cross-linked and disordered structure (illustration). Structural preservation and cross-linking gradients can be controlled through process parameters, such as pressure, working gas-flow and applied electrical output; so that one can also construct so called gradient layers; i.e with increasing degree of crosslinking over the thickness.



Comparison of the structures of plasma polymers and conventional polymers

Out of this origination mechanism from plasma polymers there results special layer characteristics that are qualified for a multitude of applications:

- excellent coating adhesion on almost all substrates
- chemical, mechanical and thermal stability
- high barrier effect

Applications from plasma polymer coatings are as follows:

- scratch resistant coatings
- corrosion protection

- anti-bonding, anti-soiling coatings
- barrier layers

Further applications are in preparation at IFAM.

Within the bounds of its function as service provider in technology transfer, IFAM offers its resources for the processing of the above-mentioned industrial questions up to series production. Our service comprises consultation, process development, sampling and industrial installation through pilot terotechnology.

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CONTENT

plasma polymerization

Wikipedia

plasma polymerization

Plasma polymerization uses plasma sources to generate a gas discharge that provides energy to activate or fragment gaseous or liquid monomer, often containing a vinyl group, in order to initiate polymerization.

Plasma polymerization can be used to deposit polymer thin films. By selecting the monomer type and the energy density per monomer, known as Yasuda parameter, the chemical composition and structure of the resulting thin film can be varied in a wide range.

Polymers obtained from plasma polymerization differ from that of conventional 'wet-chemistry' techniques. Depending on the type of the reactor, deposition conditions (discharge power, monomer flow- rate, deposition time)and substrate position, the resulting surface chemistries formed may differ. This technique is useful in applications such as biomedical whereby controlling and modifying surface become important.

Several advantages of plasma polymerized films include: 1. The ability to surface modify almost any substrates (glass, polymers, metals etc) without affecting the bulk properties 2. A large range of monomers with different functional groups are available 3. Surfaces formed are relatively pinhole-free 4. Good surface uniformity and relatively easy one-step procedure.

Mentioned In

plasma polymerization is mentioned in these AnswerPages:

Plasma processing polymerization
surface engineering radical (chemistry)

Plasma etching

From Wikipedia, the free encyclopedia

Plasma etching is a form of plasma processing in which a high-speed stream of plasma is shot (in pulses) at a metal. The atoms of the shot element embed themselves at or just below the surface of the target. The physical properties of the target are modified in the process.

Plasma etching is also used in semiconductor manufacturing where it is employed for pattern transfer at different stages of the device processing: e.g. trench etch, gate etch of the MOS transistors or contact hole etch.

Retrieved from "http://en.wikipedia.org/wiki/Plasma_etching"

Categories: Technology stubs | Plasma processing